

OPDP Update on Oversight of Prescription Drug Promotion

Thomas Abrams
Director

Office of Prescription Drug Promotion
Food and Drug Administration
October 1, 2012



Topics

- Operations and Reorganization Update
- Policy and Guidance Development
- Enforcement Analysis and Examples

Office of Prescription Drug Promotion (OPDP)

- Formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC)
- September 2011 - DDMAC was reorganized and elevated to an office structure (OPDP) which consists of:
 - Immediate Office
 - Division of Professional Drug Promotion (DPDP)
 - Division of Consumer Drug Promotion (DCDP)
- OPDP alignment based on functional areas
 - Review functions
 - Policy and support functions

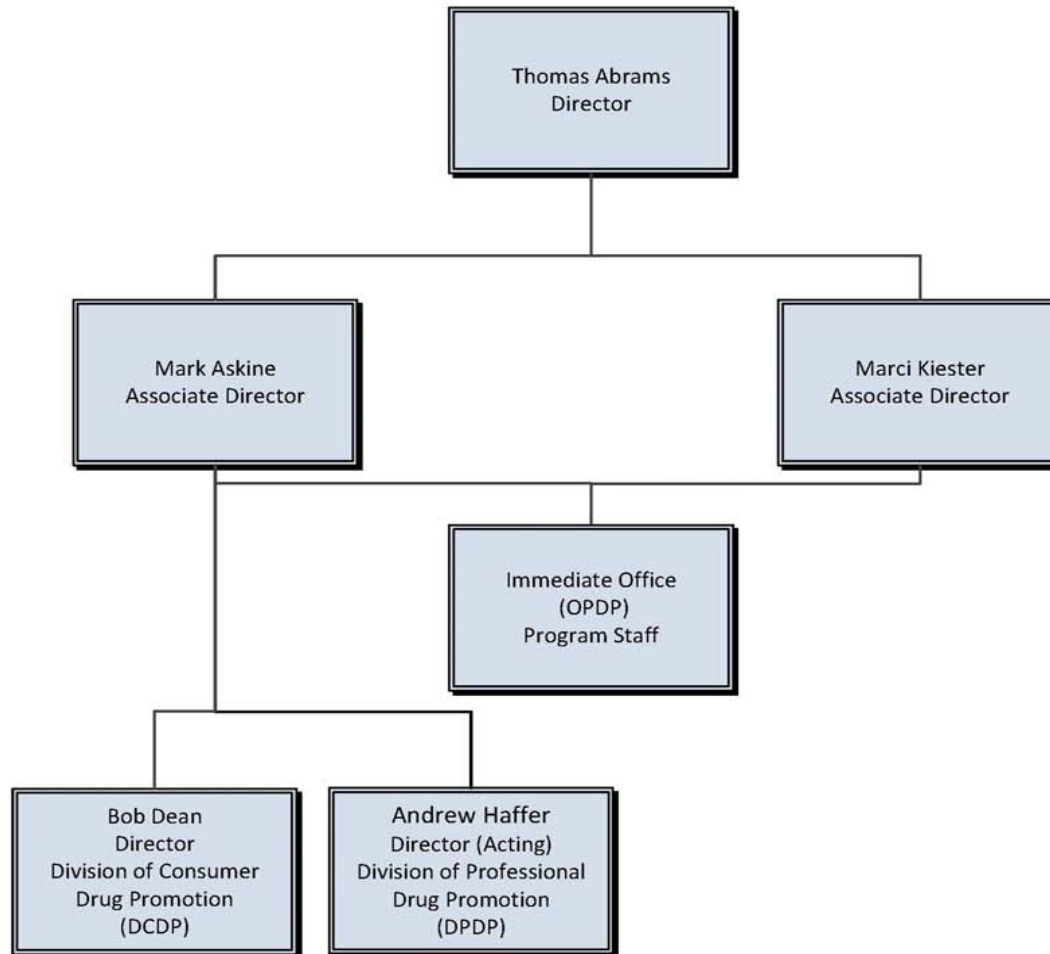
Office of Prescription Drug Promotion

- Immediate Office
 - Office Director (Thomas Abrams)
 - Associate Office Director (Mark Askine)
 - Review Functions
 - Division of Professional Drug Promotion
 - Division of Consumer Drug Promotion
 - Associate Office Director (Marci Kiester)
 - Policy and Support Functions
 - Regulatory Counsel Team
 - Social Science Research Team
 - Project Management Team

Office of Prescription Drug Promotion

- Divisions
 - Division of Professional Drug Promotion
 - Division Director (Andrew Haffer)
 - 4 Review Teams and Team Leaders
 - Division of Consumer Drug Promotion
 - Division Director (Robert Dean)
 - 4 Review Teams and Team Leaders

Office of Prescription Drug Promotion (OPDP)



Top Priorities of OPDP

- Policy and guidance development
- Labeling reviews
- Core launch reviews and TV ad reviews
- Enforcement
- Training and communications

Note all are top priorities and not in any rank order

Guidance Panel in Afternoon Session

- *DTC Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program*
- *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*
- *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*

Guidance Development Plans

- Revising current draft guidances
 - *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*
 - *Presenting Risk Information in Prescription Drug and Medical Device Promotion*
- Exploring and discussing other areas of interest
 - Health care economic information/formularies
 - Medical practice guidelines
 - Comparative claims
 - Scientific exchange
 - FR Notice seeking comments
- Working on Internet/social media promotion

Enforcement



Surveillance

- Disseminated materials submitted to FDA
 - Post-marketing reporting requirements (Form FDA 2253)
- Conference attendance
- Complaints
- Broad surveillance of materials
- Healthcare Professional Outreach Initiative
 - Bad Ad Program

The Bad Ad Program

- FDA-sponsored outreach program designed to increase awareness of healthcare professionals (HCPs) about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading
- When HCPs recognize misleading drug promotion, they can help put a stop to it by reporting it to FDA:
 - Call
 - **855-RX-BadAd**
 - E-mail
 - **BadAd@fda.gov**

The Bad Ad Program

- While the program is targeted at HCPs, it does not limit the type of misleading promotional materials HCPs can report to us
 - Healthcare professionals can recognize misleading DTC promotion and report it
 - Many of the Bad Ad complaints received by OPDP (and falling under our purview) have addressed potentially misleading DTC advertising and promotion

The Bad Ad Program: Year 1

- Sent Dear HCP letter to 33,000+ physicians and press release announcing Bad Ad Program
- Developed educational brochure, video, and reminder magnet to educate HCPs about how to recognize and report concerning prescription drug promotion
- Staffed exhibits at 15 medical conferences across the country to speak with HCPs about how they can help stop misleading drug promotion
 - Began series of presentations at U.S. teaching hospitals
- Hosted live Bad Ad webinar for medical and pharmacy professionals

The Bad Ad Program: Year 2 and Current Efforts

- Running journal ad campaign
- Developing web-based continuing education program for the nation's healthcare professionals
- Actively pursuing opportunities to enhance student education (medical/pharmacy/nursing)
- Continuing to present at major U.S. teaching institutions and exhibiting at medical conventions to increase awareness
- Participated in webcast for FDA's Expert Commentary Series on Medscape

Risk-Based Enforcement Approach

- Focus on the impact on public health including:
 - Newly approved products
 - Products with significant risks
 - Products cited for violations in the past
 - Products cited in complaints
 - Products promoted with far reaching campaigns

Most Common Violations

January 2011 – August 2012

- Omission and minimization of risk information
- Misleading efficacy claims
- Misleading superiority claims
- Promotion of unapproved uses of drugs (includes broadening of the indication)

Copaxone Warning Letter

- Medical convention exhibit panels and DTC websites
- Violations included
 - Overstatement of efficacy
 - Broadening of indication
- Indication
 - Reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis (RRMS), including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis

Copaxone Warning Letter

“David Kyle” webpage: **“Running, Swimming and Biking Against Multiple Sclerosis”**

Before Copaxone

- “It’s hard to believe that just a few years ago, this energetic and dynamic athlete had to use a cane for mobility and often could barely muster enough energy to work half a day. This was the case for David, who was diagnosed with multiple sclerosis (MS) in 2002. David awoke one morning experiencing numbness in his toes.”
- “Over the course of a few weeks, the numbness moved up his body and he eventually became partially paralyzed from the chest down. The symptoms subsided briefly only to return just six months later, this time advancing to his entire right side.”

Copaxone Warning Letter

After Copaxone

- “With the help of his doctor, David began COPAXONE® (glatiramer acetate injection) therapy in 2003”
- “After a year and a half of hard work and determination, David was the USA Triathlon National Champion in the physically challenged category.”
- David went on to compete and win numerous national and international triathlons from 2005-2008.



Copaxone Warning Letter

Overstatement of Efficacy/Broadening of Indication

- Claims imply that Copaxone reverses patients' disability and enables them to lead an active lifestyle, return to work, and/or accomplish great athletic feats.
- Broadens indication by implying that Copaxone is approved to treat **all** types of MS.
- Start date of therapy (2003) implies effectiveness beyond three years of data included in the PI.

EpiPen Warning Letter

- DTC television advertisement
- Overstatement of efficacy
- Indication
 - Indicated in the emergency treatment of allergic reactions (Type 1) including anaphylaxis to stinging insects... and biting insects..., foods, drugs....
 - Intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis....
 - Intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care
- Most important information section of Patient Labeling
 - When you have an allergic reaction (anaphylaxis) use the EpiPen ... right away and immediately go to your doctor or emergency room for more medical treatment

EpiPen Warning Letter

- TV ad included the following:
 - Mother: “Excited for Max’s birthday? Should be pretty awesome.”
 - Son: “Yeah!”
 - Mother: “Even with your peanut allergy and a cake made of who-knows what.”
 - Mother: “Because we’re prepared, right Jake?”
 - Son: “Yup!”
 - Mother: “With EpiPen.”
- Supers (over visual)
 - EpiPen (epinedrine) Auto-Injector can’t eliminate the risk of anaphylaxis

CLIENT: MYLAN SPECIALTY L.P.
PRODUCT: EPIPEN BRANDED
AGENCY: GSW NEW YORK
SPOT TITLE: "MAX/BRANDED/PEOPLE"
ISCI CODE: **DYEP0011000**

DURATION: 60 SEC

DATE: 04.03.2012

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OPDP Web Resources

- OPDP home page
 - <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm>
- OPDP organization listing
 - <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm154886.htm>
- OPDP guidances
 - <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm#Guidances>
- Warning and untitled letters
 - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

OPDP Contact Information

- **Telephone Number**
 - 301-796-1200
- **Fax Numbers**
 - 301-847-8444
 - 301-847-8445
- **Submission Address**
 - Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266